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10/528,330	02/02/2006	Kim Borch	10312.204-US	5006

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EXAMINER	
BADR, HAMID R	

ART UNIT	PAPER NUMBER
1781	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patents-US-NY@novozymes.com

Office Action Summary	Application No.	Applicant(s)	
	10/528,330	BORCH ET AL.	
	Examiner	Art Unit	
	HAMID R. BADR	1781	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' amendment filed 4/12/2010 is acknowledged.

2. Claims 25-47 are being considered on the merits.

Claim Objections

Claims 28-29, 33-34, and 40-41 are objected to for containing the wrong genus name. In these claims Magnaporthecease (Family name) should be changed to Magnaporthe (Genus name). Correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 25-29 and 43-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 25 is indefinite for "heating the dough". It is not clear whether "heating" is done for the purpose of cooking the dough or "heating" is conducted at a lower temperature for the purpose of activating an enzyme. In other words, it is not clear whether "heating" implies an incubation stage at a specific temperature.

6. Claim 43 is indefinite for "increasing the volume" and "improving the color". The terms "increase" and "improve" are relative terms which render the claim indefinite.

The terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear over what standard this is to be "increased" or "improved".

7.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 7-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Negishi et al. (JP 2622563; Machine translation, hereinafter R1) in view of JP 58190346 A (hereinafter R2) and Inoue et al. (US 4,567,046; hereinafter R3)

2. R1 discloses the use of lipoxygenase in an amount of 50-500 unit per gram of wheat flour. R1 discloses that such a flour will bring about an increase in the volume of bread and its whiteness. Bread of high quality is produced using the flour (Abstract).

3. R1 gives an example of mixing the lipoxygenase and flour so that the flour contains about 100 units of the activity of the enzyme . The prepared flour is then used in bread making by the straight dough method (page 4, machine translation, Example 1). R1 gives the improved characteristics of the baked bread containing lipoxygenase in Table 2, page 5 (machine translation).

4. R1 discloses using wheat lipoxygenase in baking. However, despite the fact that applicants have provided a specific fungal lipoxygenase from the species disclosed and claimed, this does not provide a patentable distinction over the lipoxygenase disclosed by R1 as also having the property of increasing the bread volume and its crumb whiteness, absent any clear and convincing evidence and/or arguments to the contrary. The USPTO does not possess the facilities to test lipoxygenases. However, a reasonable rejection has been set forth and thus the burden shifts to applicant to demonstrate that the lipoxygnease of the reference does not, in fact, have the same effect on bread volume and crumb color as that of the claimed lipoxygenase. Alternatively, given the specific teachings of R1; one would have been motivated to routinely screen out the identified lipoxygenase and utilize such lipoxygenase within the known methods of R1.

5. R1 is silent regarding the use of a lipolytic enzyme active on polar lipids in a dough.

6. R2 discloses use of lipoxygenase together with lisophosphatidine (LPA) which is enzymatically prepared from soybean lecithin, its salt or the phospholipid mixture having high LPA content in flour which is made into a dough (Abstract)

7. Lysophosphatidine, as disclosed by R2, is prepared enzymatically from soybean lecithin or a phospholipid mixture. It is noted that the action of a phospholipase is required to hydrolyze lecithin or mixture of phospholipids, therefore, it would be obvious to include phospholipase and its substrate phospholipids into the dough for the generation of lysophosphatidine in situ.

8. R2 discloses that the inventive composition improves the specific volume, appearance and the texture of the baked bread.

9. R2 is silent regarding the addition of a lipolytic enzyme active on polar lipids in a dough.

10. R3 discloses the use of soybean lecithin and emulsifiers in combination with phospholipase A (PL-A) (Col. 3, lines 23-30). It is noted that this enzyme is a lipolytic enzyme active on polar lipids such as phospholipids.

11. R3 teaches that the bread improver (containing phospholipase A) can be used in the production of bread by either the sponge dough process or the straight process (col. 3, lines 35-38).

12. R3 discloses that phospholipase A (PL-A) is usually added to the ingredients of dough for bread prior to the mixing thereof. Alternatively PL-A may be mixed with either wheat flour or a bakers flour mix containing various auxiliary ingredients. The alternative method has the advantage in that the need for weighing PL-A and adding a suitable amount of PL-A to the ingredient of dough every time the bread-making is done is saved, and a gradual enzymatic reaction is performed during storage (Col. 2, lines 57-65). Limitations of claims 15-17 are met.

13. It is noted that R3 is silent regarding the claimed phospholipase from *Fusarium oxysporum*. However, the claimed phospholipase from *Fusarium oxysporum* was known in the art at the time the invention was made. Applicants may refer to WO 98/26057 which discloses the phospholipase of *Fusarium oxysporum*.

14. R3 discloses that the bread produced according to the inventive process has a large volume and is suitably soft. The bread can also be stored for a prolonged period without undergoing much staling (Col. 4, lines 8-13).

15. Given that R1 discloses using lipoxygenase to bring about an increase in the volume of the bread as well as its whiteness and R3 discloses using phospholipase in order to produce bread with large volume that is suitably soft and does not stale for prolonged periods, it would have been obvious to one of ordinary skill in the art to add the lipoxygenase and phospholipase in synergistic amounts to produce bread with optimal volume while still possessing optimal whiteness, softness, and anti-staling properties.

16. R1 and R2 are clearly teaching the combination of lipoxygenase and a hydrolyzed phospholipid such as lisophosphotidine (LPA) and the effect of this combination in improving the volume, texture and color of the baked bread. R3 is clearly teaching that a phospholipase can be included in a lecithin containing formulation. It is obvious that the enzymatically prepared LPA that is taught by R2, can be clearly prepared by incorporating a phospholipase into the dough containing lecithin to generate the lysophosphatidine in situ. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to combine a lipoxygenase and a lipolytic enzyme active on polar lipids to bring about synergistic effects on the volume and crumb color of the baked products. Absent any evidence to contrary and based on the combined teachings of the cited references there would be a reasonable

expectation of success in creating such a combination of enzymes for the purpose of improved bread quality.

17. **Claims 25-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strobel et al. (US 3,711,297; hereinafter R4) in view of JP 55153549-A (Abstract, hereinafter R5).**

18. R4 discloses that activating the natural enzymes of flour by water treatment and incubation at an optimal temperature produces a flour which will result in good volume, texture, crumb color characteristics and a moist quality. (Abstract)

19. R4 teaches that the water slurry treatment process allows the naturally occurring wheat flour enzymes, such as lipases, phospholipases and lipoxidases (lipoxygenase) to react with hydrophobic lipid layers surrounding the starch granules. (col. 2, line 65 to col. 3, line13).

20. R4 discloses that lipid hydrolysis and oxidation by the natural enzymes produce partial glycerides, free fatty acids, lyso phosphatides and lipoproteins (by the interaction of oxidized lipid with the protein) which are either emulsifiers themselves or are components of the emulsifier systems. All four species aid in stabilizing the cell structure of the batter during baking.

21. The action of lipoxidase (lipoxygenase) (oxidation of lipids), lipase (hydrolysis of non-polar lipids) and phospholipase (hydrolysis of polar lipids) in improving the volume, crumb color, and texture and taste of the baked product is discloses by R4. Therefore, adding lipoxygenase and lipase or phoshpholipase to the dough or flour, for the same purpose of increased volume, and improved crumb color, would have been obvious to

an artisan. Addition of these enzymes to the dough or flour will ensure enough activity of such enzymes for the desired functional properties of the dough.

22. However, despite the fact that applicants have provided a specific fungal lipoxygenase from the species disclosed and claimed, this does not provide a patentable distinction over the lipoxygenase disclosed by R4 as also having the property of increasing the bread volume and its crumb whiteness, absent any clear and convincing evidence and/or arguments to the contrary. The USPTO does not possess the facilities to test lipoxygenases. However, a reasonable rejection has been set forth and thus the burden shifts to applicant to demonstrate that the lipoxygnease of the reference does not, in fact, have the same effect on bread volume and crumb color as that of the claimed lipoxygenase. Alternatively, given the specific teachings of R4; one would have been motivated to routinely screen out the identified lipoxygenase and phospholipase and utilize such lipoxygenase within the known methods of R4.

23. R4 is silent regarding the synergistic effect of lipoxidase, lipase or phospholipase in the dough.

24. R5 discloses a method comprising adding lipoxidase (lipoxygenase) and lipase to unbleached flour. R5 discloses that bread, breadcrumb, noodle etc. having excellent color and flavor can be prepared from unbleached flour.

25. R5 further discloses that the combination of lipase and lipoxidase together show synergistic effect.

26. It is clearly disclosed by R4 that lipoxidase, lipase and phoshpholipase improve properties of the baked product such as volume, texture, and crumb color. The

synergistic effect of the combination of these enzymes, on the properties of the baked products, is also disclosed by R5. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to combine the effect of lipoxygenase, phospholipase or lipase for the same purpose of improving the volume, crumb color, texture, and flavor of baked products. Absent any evidence to contrary and based on the combined teachings of the cited references there would be a reasonable expectation of success in creating such a combination of enzymes for the purpose of improving the quality of baked products.

Response to Arguments

Applicants' arguments have been thoroughly reviewed. These arguments are not deemed persuasive for the following reasons.

1. Applicants argue that even if a prima facie case is assumed to have been established, such a prima facie case is overcome by the unexpected results achieved with the instant invention, i.e., the synergistic effect of the combination of the lipoxygenase derived from Ascomycota and the lipolytic enzyme.

a. By referring to the rejection over R1 in view of R2 and R3 it is clear that the combination of lipoxygenase and phospholipase has been implicated in improving the loaf volume, texture and crumb color of bread. The instant claims also recite the combination of these two enzymes for the same purpose of improving the loaf volume,

texture and crumb color of the baked bread. Therefore, it does not appear that any new result has been obtained.

2. Applicants argue that in Example 1 of the specification as filed, the reference bread containing either lipoxygenase or phospholipase has a specific volume which is less than the volume obtained by the combination of both enzymes.

a. By referring to rejection over R4 in view of R5, the synergy is clearly disclosed. The teachings of R5 is specifically fundamental in disclosing the synergistic effect of lipoxidase and lipase. Therefore, it was known that the combination of an oxidative enzyme and a lipolytic enzyme would bring about a synergistic effect regarding the improvement in bread volume, texture and crumb color. The synergistic effect that the applicants are referring to was therefore known in the art.

b. As set forth in rejections, the disclosures by R1 in view of R2 and R3 are all directed toward the use of lipoxygenase and phospholipase. Further, they all teach the effect of such enzymes on the loaf volume and crumb color of the baked product. Therefore their effect in a single composition to be used for the same purpose of volume increase and improvements in the crumb color would be synergistic and obvious.

Furthermore, it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in

cast iron.); and *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held *prima facie* obvious). (MPEP 2144.06)

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R. Badr
Examiner
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